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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,560	01/29/2004	Mariagrazia Pizza	002441.00076	8267

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,560	PIZZA ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/265,742.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III, claim 50 in the response to restriction requirement and amendment filed on December 28, 2006 is acknowledged. In the amendment, claims 20-49, 51 and 52 have been cancelled, claim 50 has been amended, and a new claim 53 has been added. Therefore, claims 50 and 53 are examined. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. In the first preliminary amendment filed January 29, 2004, a substitute specification to correct clerical, spelling and grammatical errors has been filed, and the substitute specification has been entered.

3. In the second preliminary amendment filed December 3, 2004, a paper copy of Sequence Listing has been filed, and CRF (computer readable form) of Sequence Listing has been entered.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 50 and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U. S. Patent 6,713,072. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 50 and 53 in the instant application disclose a method of immunizing a human against pertussis comprising administering an effective amount of a vaccine comprising a therapeutically effective quantity of a polypeptide comprising the S1, S2, S3, S4 and S5 subunits of pertussis toxin having the same arrangement and configuration as that present in the natural pertussis toxin, wherein the S1 subunit is modified by the substitution of glutamic acid at position 129 with glycine and the substitution of arginine at position 9 with another natural amino acid such as glycine. This is an obvious variation in view of claims 1-6 of the patent which disclose an immunologically active modified pertussis toxin comprising the S1, S2, S3, S4 and S5 subunits of pertussis toxin having the same arrangement and configuration as that present in the natural pertussis toxin, wherein the S1 subunit is modified by the substitution of glutamic acid at position 129 with glycine and the substitution of arginine at position 9 with another natural amino acid; an antipertussis vaccine comprising a therapeutically effective quantity of at least one immunologically active modified pertussis toxin; a method of immunizing a human against pertussis comprising administering an effective amount of the antipertussis vaccine. Both the claims of instant application and the claims of the patent are directed to a method of immunizing a human against pertussis comprising administering an effective amount of a vaccine comprising a therapeutically effective quantity of a polypeptide comprising the S1, S2, S3, S4 and S5 subunits of pertussis toxin having the same arrangement and configuration as that present in the natural pertussis toxin, wherein the S1 subunit is modified by the substitution of glutamic acid at

position 129 with glycine and the substitution of arginine at position 9 with another natural amino acid. Thus, claims 50 and 53 in present application and claims 1-6 in the patent are obvious variations of a method of immunizing a human against pertussis comprising administering an effective amount of a vaccine comprising a therapeutically effective quantity of a polypeptide comprising the S1, S2, S3, S4 and S5 subunits of pertussis toxin having the same arrangement and configuration as that present in the natural pertussis toxin, wherein the S1 subunit is modified by the substitution of glutamic acid at position 129 with glycine and the substitution of arginine at position 9 with another natural amino acid.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK

March 14, 2007